



January 21, 2005

Documents Management Branch (HFA-305)
Attn: Docket No. 2004D-0510
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comments on Draft Guidance Entitled "Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Live and Perishable Fish and Fishery Products for Export to the European Union and the European Free Trade Association" [Docket 2004D-510]

Dear Sir or Madam:

The Boston Lobster Company has been shipping live lobsters around the world since its inception in 1986. Last year, we sent approximately 200 shipments to the European Union (EU) countries. For each shipment, we were issued a EU Export Health Certificate (Certificates) by the Food and Drug Administration (FDA).

Our facility has operated under the FDA's Hazard Analysis Critical Control Point (HACCP) program since it was enacted in 1997. Under this program, each seafood company is required to develop an operating plan that ensures all seafood in the facility is received, handled, stored, and shipped safely. Our company, like all others, instituted a self-monitoring plan that guarantees seafood is handled safely. Periodic inspections by an FDA food safety inspector verify compliance with our own safety program. Since we implemented our plan, we have followed the FDA's safety guidelines, regularly pass their periodic inspections and are in good standing with the FDA. Compliance with the above criteria allows us to obtain Certificates in advance from the FDA.

We are strongly opposed to the proposed referral program to the National Oceanic and Atmospheric Administration (NOAA) by the FDA. Our overseas shipments are completely dependent upon having Certificates available as needed. We are concerned that any changes or disruptions to a system that works well currently could devastate our multi-million dollar export business.

2004D-0510

Will ship anywhere in the World

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Time Sensitive

Shipping a live and highly perishable commodity like live lobsters overseas is extremely risky. It involves adhering to a strict schedule ensuring the product is packed out of our salt water holding facility right before it is delivered to our freight forwarding partners. This requires one of our crews to work at night to make the 5:00 AM freight cutoff deadlines. The product is then trucked to the New York Metropolitan area where it is loaded on the appropriate airline. Any delays caused by traffic, weather, cancelled air flights or unavailable health certificates could result in not only lost business, but hundreds of thousands of dollars in mortality losses. It is imperative that nothing disrupts our rigid schedule.

The FDA has not stated in either its November 26, 2004 Federal Register Notice or in its Guidance to the Industry that we will still be able to receive the necessary Certificates in a timely fashion under its proposal. We cannot support an experiment that may irreparably harm our business.

Competition

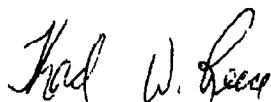
The seafood business in general and the live lobster industry specifically is very price sensitive. Ten to fifteen cents per pound will make the difference in selling a particular customer or not. There is increasing competition from not only US suppliers, but Canadian seafood companies are bypassing the US market and shipping directly to the EU. Canadian export companies receive Certificates at no charge from the Canadian Food Inspection Agency (CFIA). US companies are able to compete largely because we have more international flights allowing faster transport times and lower overall mortality. This advantage could be offset by any cost increases associated with the proposed program.

Prior to the implementation of the FDA HACCP program, we worked with NOAA in obtaining certificates and shipping to the EU. It was extremely difficult working under this arrangement for two main reasons. First, you could not rely on the inspector showing up when needed. Secondly, you never knew until you received an invoice three weeks later how much a particular inspection cost. We had some instances where we were billed \$300 for a ten-minute, in-plant inspection. Additional costs such as these could very well make us uncompetitive resulting in lost business.

Conclusion

As the saying goes, "If it isn't broken, don't fix it." The current system of obtaining Certificates from the FDA for shipping to the UE under a self-regulated HACCP program works very well. In our opinion, the Proposed Referral Program introduces too many uncertainties into such a vital facet of our business and we cannot advocate making sweeping changes. We certainly understand that issuance of Certificates by the FDA is a time consuming task. We would support paying a nominal fee for our Certificates if it would ensure business continuing as usual. We strongly urge the FDA to reconsider their proposal.

Yours truly,



Thad W. Reece
Managing Director